

3-9-06

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 26 JAN 2006

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Applicant's or agent's file reference PC/DMP13655PC	<b>FOR FURTHER ACTION</b> See Form PCT/PEA/416	
International application No. PCT/GB2004/002905	International filing date (day/month/year) 05.07.2004	Priority date (day/month/year) 03.07.2003
International Patent Classification (IPC) or national classification and IPC C01B39/02, A61K9/14, A61K7/48		
Applicant THE UNIVERSITY COURT OF THE UNIVERSITY OF ST ...		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 10 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of <sup>11</sup> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 03.05.2005	Date of completion of this report 24.01.2006	
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Rigondaud, B Telephone No. +31 70 340-2327 	

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# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/GB2004/002905

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## Box No. I Basis of the report

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

### Description, Pages

1-10, 12-27	as originally filed
11	received on 18.05.2005 with letter of 18.05.2005

### Claims, Numbers

1-40	received on 18.05.2005 with letter of 18.05.2005
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### Claims, Pages

1-31	as originally filed
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### Drawings, Sheets

1/5-5/5	as originally filed
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- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/002905

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 37-40

because:

☒ the said international application, or the said claims Nos. 37-40 relate to the following subject matter which does not require an international preliminary examination (specify):

**see separate sheet**

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/002905

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	2-9,11-18,20-36,40
	No: Claims	1,10,19,37-39
Inventive step (IS)	Yes: Claims	
	No: Claims	1-40
Industrial applicability (IA)	Yes: Claims	1-36
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 37-40 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- D1: WEN-XIANG ZHANG ET AL: "REVERSIBLE AND IRREVERSIBLE ADSORPTION OF NITROGEN MONOXIDE ON COBALT ION-EXCHANGED ZSM-5 AND MORDENITE ZEOLITES AT 273-523 K" JOURNAL OF THE CHEMICAL SOCIETY. FARADAY TRANSACTIONS, ROYAL SOCIETY OF CHEMISTRY, CAMBRIDGE, GB, vol. 91, no. 4, 21 February 1995 (1995-02-21), pages 767-771, XP000488283 ISSN: 0956-5000
- D2: ZHANG, WEN XIANG ET AL: "Removal of nitrogen monoxide on copper ion-exchanged zeolites by pressure swing adsorption" LANGMUIR, vol. 9, no. 9, 1993, pages 2337-2343, XP002302082
- D3: RUDOLF T ET AL: "Adsorption and Desorption Behavior of NO on H-ZSM-5, Na-ZSM-5, and Na-A as Studied by EPR" JOURNAL OF MAGNETIC RESONANCE, ACADEMIC PRESS, ORLANDO, FL, US, vol. 155, no. 1, March 2002 (2002-03), pages 45-56, XP004407819 ISSN: 1090-7807
- D4: DATABASE COMPENDEX [Online] ENGINEERING INFORMATION, INC., NEW YORK, NY, US; SASAKI YUKICHI ET AL: "Effect of iron modification on

the adsorption property of nitrogen monoxide on zeolite Y" XP002302084  
Database accession no. EIX98204132975

- D5: PAVELIC K ET AL: "Immunostimulatory effect of natural clinoptilolite as a possible mechanism of its antimetastatic ability." JOURNAL OF CANCER RESEARCH AND CLINICAL ONCOLOGY. JAN 2002, vol. 128, no. 1, January 2002 (2002-01), pages 37-44, XP002302085 ISSN: 0171-5216
- D6: US 2002/054919 A1 (HOCHWALT MARK A ET AL) 9 May 2002 (2002-05-09)
- D7: WO 95/24908 A (COMEDICUS INC ; US HEALTH (US)) 21 September 1995 (1995-09-21)
- D8: WO 01/21148 A (KROENCKE KLAUS DIETRICH ; KUHN ANNEGRET (DE); KOLB BACHOFEN VICTORIA () 29 March 2001 (2001-03-29)

## **1- Remark:**

For the assessment of the present claims 37-40 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

## **2- Novelty:**

### **2-1 Independent claims 1, 10 and 19:**

Document D5 points out in its abstract (see D5, page 37, left-hand column) that zeolites, among other properties, reversibly bind small molecules such as nitric oxide, making them interesting for pharmaceutical industry and medicine.

Therefore, the subject-matter of independent claims 1, 10 and 19 is not new in the sense of Article 33(2) PCT.

**2-2 Claims 37-39:**

Claim 37 refers to a method of releasing nitric oxide from a zeolite material comprising releasibly adsorbed nitric oxide. This zeolite is then contacted with a medium into which nitric oxide is released. Claim 37 precises that this release is performed inside an animal body or in a non-body application.

Interest of zeolites that reversibly bind nitric oxide for pharmaceutical industry and medicine is known of D5 (see point 2-1).

In the case of releasing nitric oxide in a non-body application, document D2 still appears to be a novelty destroying document against claim 37 and its dependent claim 39.

Therefore, the subject-matter of claims 37-39 is not new over D5 and/or D2 (Article 33(2) PCT).

**3- Inventive step:**

**3-1 Dependent claims 2-8 and dependent claims 11-17:**

The subject-matter of dependent claims 2-8 and dependent claims 11-17 appears to concern design options well-known in the field of zeolites (see for example D2-D4) that a man skilled in the art, starting from the teaching of D5, would consider without involving the exercise of an inventive step, and therefore does not seem to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements in respect to novelty and inventive step.

**3-2 Independent claim 9:**

Zeolites which reversibly bind nitric oxide are interesting for pharmaceutical industry and medicine (D5, page 37, abstract). Use of a pharmaceutical carrier combined with that zeolite in order to obtain this pharmaceutical preparation is regarded as a normal

procedure in that field.

The subject-matter of claim 9 does therefore not involve an inventive step (Article 33(3) PCT).

**3-3 Dependent claims 18 and 20:**

D5 refers to the reversibly adsorption of nitric oxide that makes zeolites interesting for pharmaceutical industry and medicine.

Use of nitric oxide-releasing polymers to treat or prevent the onset of restenosis and related disorders is known from D7 (see abstract). Moreover, nitric oxide delivery means described in D7 (see page 8, lines 8-14) encompasses forms such as stent, catheter and self-adhering means.

It would be obvious to the person skilled in art, looking for an alternative nitric oxide-releasing agent, to use a zeolite disclosed in D5 with a corresponding effect, thereby arriving to the subject-matter of claims 18 and 20.

The subject-matter of claims 18 and 20 does therefore not involve an inventive step (Article 33(3) PCT)

**3-4 Claims 21, 22 and 30:**

Document D8 is considered as being the closest prior art to the subject-matter of claims 21, 22 and 30. D8 relates to a composition containing a NO-liberating compound, its preparation and its use as dermatological and/or cosmetic product (see D8, abstract and claims 1, 2 and 13). Nitrogen monoxide releasing compounds disclosed in D8 might be organic or anorganic compounds and liberate NO either spontaneously or under a biochemical or physical influence (see D8, page 4 to page 5).

The distinguishing feature of claims 21, 22 and 30 over D8 is the use of a zeolite as NO-releasing material.

There seems to be no technical effect related to this difference. The objective problem



seems to seek an alternative to a NO-releasing material according to D8.

As previously disclosed in paragraph 2-1, document D5 refers to the reversibly adsorption of nitric oxide which makes zeolites interesting for pharmaceutical industry and medicine. It would be obvious to the person skilled in the art, looking for an alternative nitrogen monoxide releasing adsorbent, to use a zeolite disclosed in D5 with a corresponding effect in a method according to D8, thereby arriving to the subject-matter of claims 21, 22 and 30.

The subject-matter of claims 21, 22 and 30 does therefore not involve an inventive step (Article 33(3) PCT).

**3-5 Dependent claims 23-29:**

The subject-matter of dependent claims 23-29 appears to concern design options well-known in the field of zeolites (see for example D2-D4) that a man skilled in the art, starting from the teaching of D5, would consider without involving the exercise of an inventive step, and therefore does not seem to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements in respect to novelty and inventive step.

**3-6 Claims 31-36:**

Zeolites which reversibly bind nitric oxide are interesting for pharmaceutical industry and medicine (D5, page 37, abstract).

Claim 31 relates to a method of preparing a medical article, or cosmetic and/or personal hygiene product comprising a zeolite by contacting it with nitric oxide is therefore regarded as a normal procedure and cannot be considered as involving an inventive step.

The subject-matter of claims 32-36 appears to concern design options that a skilled man working on the adsorption of nitric oxide by a zeolite would consider, and therefore does not seem to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements in respect of novelty or inventive step.

**3-7 Independent claim 40:**

Document D7 is considered as being the closest prior art to the subject-matter of claims 15-18 and 31. D7 relates to a method of using NO-releasing polymers to treat, ameliorate or prevent the onset of restenosis related disorders (see page 1, lines 9-14).

The distinguishing feature of claim 40 over D7 is the use of a zeolite as NO-releasing material.

There seems to be no technical effect related to this difference. The objective problem seems to seek an alternative to a NO-releasing material according to D7.

Document D5 points out in the abstract (see D1, page 37, left-hand column) that zeolites, among other properties, reversibly bind small molecules such as nitric oxide, making them interesting for pharmaceutical industry and medicine.

It would be obvious to the person skilled in the art, looking for an alternative nitrogen monoxide releasing adsorbent, to use a zeolite disclosed in D5 with a corresponding effect in a method according to D7, thereby arriving to the subject-matter of claim 40.

The subject-matter of claim 40 does therefore not involve an inventive step (Article 33(3) PCT).

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for example, for suppository application in the treatment of severe constipation.

According to a third aspect of the present invention  
5 there is provided a zeolite material comprising releasably adsorbed nitric oxide for use in surgery and/or therapy.

According to a fourth aspect of the present invention there is provided a pharmaceutical, nutraceutical or cosmetic preparation comprising a zeolite material  
10 comprising releasably adsorbed nitric oxide together with a pharmaceutical/nutraceutical/cosmetic carrier therefor.

The present invention also provides the use of a zeolite material comprising releasably adsorbed nitric oxide in the preparation of a medicament for use in the  
15 treatment or prophylaxis of disease.

Diseases or medical conditions which may be treated include infections of the skin, including dermatophyte fungi, leishmaniasis, molluscum and papilloma virus, and mycobacterium infections. Further uses include therapeutic  
20 applications in anti-neoplastic activities, immune response modification, treatment of Raynaud's disease, wound healing and skin pigment modification. Yet further uses include treatment of restenosis, psoriasis and eczema, and skin cancer (melanoma). Therapies for other  
25 bacterial problems include the reduction of severe foot or body odour problems, and in the treatment of Methicillin Resistant Staphylococcus Aureus infections.

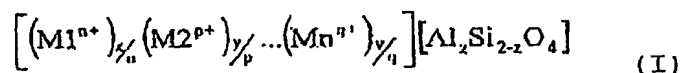
According to a sixth aspect of the present invention there is provided a medical article comprising a zeolite  
30 material.

The zeolite material of the medical article may be provided without nitric oxide loaded therein to allow

CLAIMS

1. A zeolite material comprising releasably adsorbed nitric oxide for use in surgery and/or therapy.

2. A zeolite material for use according to claim 1, wherein the zeolite has the following general formula (I):



wherein M1 and M2 ... Mn are extra framework metal cations of elements selected from the group consisting of Li, Na, K, Ca, Mg, Fe, Cu, Ru, Rh, Co, Ni, Zn and Ag, or are chosen from small organic cations such as  $N(R_1)_a(R_2)_b^+$  wherein  $R_1$  and  $R_2$  are independently selected from H,  $-CH_3$ ,  $-CH_2CH_3$ , or  $-CH_2CH_2CH_3$ , and a and b are independently 0, 1, 2, 3 or 4 such that  $a + b = 4$ ;

x ranges from zero to nz,

y ranges from zero to pz, and

v ranges from zero to qz;

subject to the condition that  $x/n + y/p + \dots + v/q = z$ ;

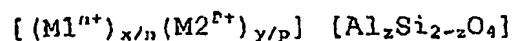
wherein

z is the number of silicon atoms replaced by aluminium atoms in the zeolite framework;

$n^+$ ,  $p^+$  and  $q^+$  are the charges of the extra framework metal cations, and may individually take the values of +1, +2 or +3.

3. A zeolite material for use according to claim 2, wherein M1 and/or M2 are  $NH_4^+$ .

4. A zeolite material for use according to any preceding claim having the following general formula (II):



(II)

wherein M1 and M2 are extra framework metal cations of elements selected from the group consisting of Li, Na, K, Ca, Mg, Fe, Cu, Ru, Rh, Co, Ni, Zn and Ag, or are chosen from small organic cations such as  $N(R_1)_a(R_2)_b^+$  wherein  $R_1$  and  $R_2$  are independently selected from H,  $-CH_3$ ,  $-CH_2CH_3$ , or  $-CH_2CH_2CH_3$ , and a and b are independently 0, 1, 2, 3 or 4 such that  $a + b = 4$ ;

x may range from zero to nz, and

y may range from zero to pz, subject to the condition that  $x/n + y/p = z$ ;

wherein

z is the number of silicon atoms replaced by aluminium atoms in the zeolite framework;

n+ and p+ are the charges of the extra framework metal cations and may individually take the values of +1, +2 or +3.

5. A zeolite material for use according to any preceding claim, wherein the zeolite is selected from the group consisting of Ni-LTA(A), Cu-LTA(A), Co-LTA(A), Mn-LTA(A), Fe-LTA, Na-LTA(A) and Cu-PHI.

6. A zeolite material for use according to any previous claim, in the form of a powder or a monolith.

7. A zeolite material for use according to claim 6, wherein said monolith is formed by compression of a

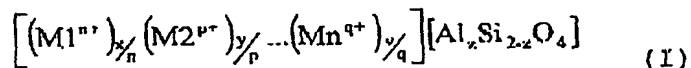
zeolite powder or by mixing a powdered zeolite with a binder.

8. A zeolite material for use according to claim 7, wherein the binder is selected from ceramic binders, polymeric binders and other polymers.

9. A pharmaceutical preparation comprising a zeolite material comprising releasably adsorbed nitric oxide according to any one of claims 1-8 together with a pharmaceutical carrier.

10. Use of a zeolite material comprising releasably adsorbed nitric oxide in the preparation of a medicament for use in the treatment or prophylaxis of disease or medical conditions.

11. Use according to claim 10, wherein the zeolite has the following general formula (I):



wherein M1 and M2 ... Mn are extra framework metal cations of elements selected from the group consisting of Li, Na, K, Ca, Mg, Fe, Cu, Ru, Rh, Co, Ni, Zn and Ag, or are chosen from small organic cations such as  $N(R_1)_a(R_2)_b^+$  wherein  $R_1$  and  $R_2$  are independently selected from H,  $-CH_3$ ,  $-CH_2CH_3$ , or  $-CH_2CH_2CH_3$ , and a and b are independently 0, 1, 2, 3 or 4 such that  $a + b = 4$ ;  
x ranges from zero to nz,  
y ranges from zero to pz, and  
v ranges from zero to qz;

subject to the condition that  $x/n + y/p + \dots + v/q = z$ ;

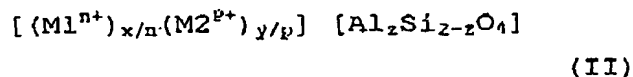
wherein

$z$  is the number of silicon atoms replaced by aluminium atoms in the zeolite framework;

$n+$ ,  $p+$  and  $q+$  are the charges of the extra framework metal cations, and may individually take the values of +1, +2 or +3.

12. Use according to claim 11, wherein M1 and/or M2 are  $\text{NH}_4^+$ .

13. Use according to any one of claims 10 to 12, wherein the zeolite has the following general formula (II):



wherein M1 and M2 are extra framework metal cations of elements selected from the group consisting of Li, Na, K, Ca, Mg, Fe, Cu, Ru, Rh, Co, Ni, Zn and Ag, or are chosen from small organic cations such as  $\text{N}(\text{R}_1)_a(\text{R}_2)_b^+$  wherein  $\text{R}_1$  and  $\text{R}_2$  are independently selected from H,  $-\text{CH}_3$ ,  $-\text{CH}_2\text{CH}_3$ , or  $-\text{CH}_2\text{CH}_2\text{CH}_3$ , and  $a$  and  $b$  are independently 0, 1, 2, 3 or 4 such that  $a + b = 4$ ;

$x$  may range from zero to  $nz$ , and

$y$  may range from zero to  $pz$ , subject to the condition that  $x/n + y/p = z$ ;

wherein

$z$  is the number of silicon atoms replaced by aluminium atoms in the zeolite framework;

$n+$  and  $p+$  are the charges of the extra framework metal cations and may individually take the values of +1, +2 or +3.

14. Use according to any one of claims 10 to 13, wherein the zeolite is selected from the group consisting of Ni-LTA(A), Cu-LTA(A), Co-LTA(A), Mn-LTA(A), Fe-LTA, Na-LTA(A) and Cu-PHI.

15. Use according to any one of claims 10 to 14, wherein the zeolite is in the form of a powder or a monolith.

16. Use according to claim 15, wherein said monolith is formed by compression of a zeolite powder or by mixing a powdered zeolite with a binder.

17. Use according to claim 16, wherein the binder is selected from ceramic binders, polymeric binders and other polymers.

18. Use according to any one of claims 10 to 17, wherein the diseases or medical conditions which may be treated include infections of the skin, including dermatophyte fungi, leishmaniasis, molluscum and papilloma virus, and mycobacterium infections; therapeutic applications in anti-neoplastic activities; immune response modification; treatment of Raynaud's disease; wound healing; skin pigment modification; treatment of rosacea; treatment of psoriasis, eczema, and skin cancer (melanoma); therapies for bacterial problems, the reduction of severe foot or body odour, and treatment of Methicillin Resistant Staphylococcus Aureus infections.

19. A medical article comprising a zeolite material, wherein the zeolite material is provided as a zeolite



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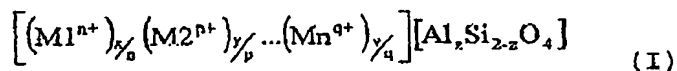
material comprising releasably adsorbed nitric oxide as claimed in any one of claims 1-8.

20. A medical article according to claim 19, wherein said medical article is chosen from a stent, catheter, wound dressing, bandage, self-adhesive plaster and patch.

21. Use of a zeolite comprising releasably adsorbed nitric oxide in a cosmetic and/or personal hygiene application.

22. A cosmetic and/or personal hygiene product comprising a zeolite which comprises releasably adsorbed nitric oxide.

23. A cosmetic and/or personal hygiene product according to claim 22, wherein the zeolite has the following general formula (I):



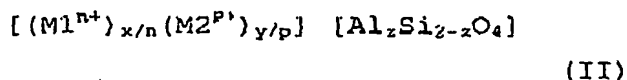
wherein M1 and M2 ... Mn are extra framework metal cations of elements selected from the group consisting of Li, Na, K, Ca, Mg, Fe, Cu, Ru, Rh, Co, Ni, Zn and Ag, or are chosen from small organic cations such as  $N(R_1)_a(R_2)_b^+$  wherein  $R_1$  and  $R_2$  are independently selected from H,  $-CH_3$ ,  $-CH_2CH_3$ , or  $-CH_2CH_2CH_3$ , and a and b are independently 0, 1, 2, 3 or 4 such that  $a + b = 4$ ;  
 x ranges from zero to nz,  
 y ranges from zero to pz, and  
 v ranges from zero to qz;  
 subject to the condition that  $x/n + y/p + \dots + v/q = z$ ;  
 wherein

z is the number of silicon atoms replaced by aluminium atoms in the zeolite framework;

n+, p+ and q+ are the charges of the extra framework metal cations, and may individually take the values of +1, +2 or +3.

24. A cosmetic and/or personal hygiene product according to claim 23, wherein M1 and/or M2 are  $\text{NH}_4^+$ .

25. A cosmetic and/or personal hygiene product according to any one of claims 22 to 24, having the following general formula (II):



wherein M1 and M2 are extra framework metal cations of elements selected from the group consisting of Li, Na, K, Ca, Mg, Fe, Cu, Ru, Rh, Co, Ni, Zn and Ag, or are chosen from small organic cations such as  $\text{N}(\text{R}_1)_a(\text{R}_2)_b^+$  wherein  $\text{R}_1$  and  $\text{R}_2$  are independently selected from H,  $-\text{CH}_3$ ,  $-\text{CH}_2\text{CH}_3$ , or  $-\text{CH}_2\text{CH}_2\text{CH}_3$ , and a and b are independently 0, 1, 2, 3 or 4 such that  $a + b = 4$ ;

x may range from zero to nz, and

y may range from zero to pz, subject to the condition that  $x/n + y/p = z$ ;

wherein

z is the number of silicon atoms replaced by aluminium atoms in the zeolite framework;

n+ and p+ are the charges of the extra framework metal cations and may individually take the values of +1, +2 or +3.

26. A cosmetic and/or personal hygiene product according to any one of claims 22 to 25, wherein the zeolite is selected from the group consisting of Ni-LTA(A), Cu-LTA(A), Co-LTA(A), Mn-LTA(A), Fe-LTA, Na-LTA(A) and Cu-PHI.

27. A cosmetic and/or personal hygiene product according to any one of claims 22 to 26 in the form of a powder or a monolith.

28. A cosmetic and/or personal hygiene product according to claim 27, wherein said monolith is formed by compression of a zeolite powder or by mixing a powdered zeolite with a binder.

29. A cosmetic and/or personal hygiene product according to claim 28, wherein the binder is selected from ceramic binders, polymeric binders and other polymers.

30. A cosmetic and/or personal hygiene product according to any one of claims 22 to 29, which is selected from a cosmetic preparation, deodorant, skin preparation, anti-aging skin preparation, hair preparation and depilatory preparation.

31. A method of preparing a medical article, cosmetic and/or personal hygiene product comprising the steps of:

i) providing a medical article, cosmetic and/or personal hygiene product which comprises a zeolite material without nitric oxide adsorbed therein, and

ii) contacting said zeolite material of said medical article, cosmetic and/or personal hygiene product with nitric oxide gas.

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32. A method according to claim 31 wherein the zeolite material is fully or partially dehydrated to remove water from the zeolite channels prior to contacting the zeolite material with nitric oxide gas.

33. A method according to claim 31 or claim 32, wherein the zeolite material is contacted with nitric oxide gas at a temperature of from  $-100^{\circ}\text{C}$  to  $50^{\circ}\text{C}$ .

34. A method according to any one of claims 31 to 33 wherein the nitric oxide is provided as substantially pure nitric oxide or as a mixture of nitric oxide and a carrier gas.

35. A method according to claim 34 wherein the carrier gas is an inert gas chosen from helium, argon or other inert gas including mixtures thereof.

36. A method according to any one of claims 31 to 35 wherein the zeolite is contacted with nitric oxide gas at a pressure of from atmosphere pressure up to a pressure of 10 bar.

37. A method of releasing nitric oxide comprising the steps of

- (i) providing a zeolite material comprising releasably adsorbed nitric oxide;
- (ii) contacting said zeolite material with a medium into which said nitric oxide is to be released, wherein the release is performed inside an animal body, topically to an animal body or in non-body applications.

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38. A method according to claim 37, wherein the release in non-body applications includes release into cell cultures.

39. A method according to claim 37 or claim 38, wherein the release is performed at room or body temperature.

40. A method of treatment or prophylaxis of an individual in need thereof comprising providing a zeolite comprising releasably adsorbed nitric oxide and contacting said zeolite with said individual.

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